

6836-152

8-27-2001

1/8

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

AUG 27 2001

Subject: Lonza Formulation DC-103  
EPA Registration No. 6836-152  
Amendment Dated: May 29, 2001  
EPA Receive Date: June 1, 2001

Attention: Ms. Christine Swick

The amendment referenced above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) to add additional organisms, marketing statements, sites, surfaces, and directions is acceptable provided you address the following comments before this product is released for shipment.

On page 4, Revise the statement, "after use to disinfect ... potable water," to read "Rinse all surfaces that come in contact with food such as counters, stovestops, and tables with potable water before reuse. Do not use this product on utensils, glassware, and dishes."

On page 5, the directions for finished floors should either be moved under the disinfection/virucidal directions section or revised to state "Allow floor(s) to remain wet for 10 minutes. Allow surface(s) to air dry."

A stamped label is enclosed for your records. Please submit one (1) copy of the final printed label before this product is released for shipment. If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch  
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL	7510C						
SURNAME	McFarlane						
DATE	8/22/01						

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**Caution.** Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

**FIRST AID**

Call a poison control center or doctor for treatment advice.  
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.

*(Note to reviewer: If container size is 5 gallons or larger, the following Environmental Hazards statements will be used:)*

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 6836-152

**LONZA FORMULATION DC-103**

One-Step Disinfectant

Cleaner – Fungicide - Mildewstat - Virucide\* - Deodorizer  
For Homes, Hospitals, Institutional and Industrial Use

Effective in the presence of 5% serum contamination

- Formulated for Effective Poultry Premise Sanitation
- Formulated for Effective Swine Premise Sanitation
- Formulated for Effective Farm Premise Sanitation
- Formulated for Effective Mushroom Farm Sanitation
- Formulated for Veterinary Practice / Animal Care / Animal Laboratory Disinfection

For use in federally inspected meat and poultry plants

- Staphylocidal • Pseudomonacidal
- Salmonellacidal • Fungicidal • Virucidal\*

**Active Ingredients:**

Octyl decyl dimethyl ammonium chloride .....	0.025%
Dioctyl dimethyl ammonium chloride .....	0.010%
Didecyl dimethyl ammonium chloride .....	0.015%
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride .....	0.034%
Inert Ingredients .....	99.916%
Total .....	100.000%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

SEE LEFT / SIDE / RIGHT / BACK PANEL FOR  
ADDITIONAL PRECAUTIONARY STATEMENTS and FIRST  
AID

EPA Reg. No. 6836-152  
EPA Establishment No. *(insert EPA Est. No. here)*  
Net Contents *(insert container size here)*

Manufactured by:  
LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410

This product contains no phosphorous.

When used as directed, LONZA FORMULATION DC-103 will deodorize surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

Cross-contamination is of major housekeeping concern. LONZA FORMULATION DC-103 has been formulated to aid in the reduction of cross-contamination in not only in hospitals, but in schools, institutions and industry.

Use LONZA FORMULATION DC-103 in federally inspected meat and poultry plants. USDA previously authorized this product as category D1 - for use on all surfaces in inedible product processing areas, nonprocessing areas, and / or exterior areas.

LONZA FORMULATION DC-103 delivers non-acid disinfectant and cleaning performance. Effective, yet economical, LONZA FORMULATION DC-103 is a heavy-duty disinfectant cleaner that disinfects, cleans and deodorizes in one labor saving step.

LONZA FORMULATION DC-103 can be used with a mop and bucket, trigger sprayers, sponge or by soaking.

LONZA FORMULATION DC-103 improves labor results by effectively controlling malodors.

Use LONZA FORMULATION DC-103 for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.

Use LONZA FORMULATION DC-103 to clean and disinfect finished floors, sinks and tubs.

Use LONZA FORMULATION DC-103 in kitchens, bathrooms and other household areas.

LONZA FORMULATION DC-103 is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.

LONZA FORMULATION DC-103 will not leave grit or soap scum.

LONZA FORMULATION DC-103 is a versatile disinfectant for Veterinarian, Animal Care and Farm Premise applications.

LONZA FORMULATION DC-103 is a complete, chemically balanced disinfectant.

LONZA FORMULATION DC-103 deodorizes by killing microorganisms that cause offensive odors.

Use LONZA FORMULATION DC-103 as a disinfectant on hard, nonporous surfaces.

Use LONZA FORMULATION DC-103 for disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.

Use LONZA FORMULATION DC-103 on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for disinfection.

LONZA FORMULATION DC-103 is a versatile cleaner and broad-spectrum disinfectant formulated for use only on non-critical instruments in Ultrasonic Baths (Ultrasonic cleaning units).

Use LONZA FORMULATION DC-103 to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.

Use LONZA FORMULATION DC-103 to clean and disinfect finished floors. Can be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.

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Use **LONZA FORMULATION DC-103** in homes, hospitals, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, bars, cafeterias, institutional kitchens, food preparation and storage areas, convenience stores, public rest rooms, institutions, schools and colleges, athletic facilities, locker rooms, dressing rooms, shower and bath areas, exercise facilities, camp grounds, play grounds, institutional and public facilities, food processing plants, USDA inspected food processing facilities, dairy farms, hog farms, poultry and turkey farms, kennels, pet animal quarters, zoos, pet shops, animal laboratories, transportation terminals, hotels and motels, factories, business and office buildings, barber shops, salons, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, airplanes, emergency vehicles, prisons, correctional facilities, and ultrasonic baths.

Use **LONZA FORMULATION DC-103** on washable hard, nonporous surfaces: floors, walls, countertops, stovetops, sinks, appliances, refrigerators, microwave ovens, plastic and other nonporous cutting boards and chopping blocks; coolers, ice chests; refrigerator meat, fruit, vegetable and egg bins; Tupperware®, cabinets, highchairs, garbage cans, refrigerated storage and display equipment, tables, picnic tables, outdoor furniture, chairs, desks, telephones, doorknobs, shower stalls, tubs and glazed tiles, whirlpool bathtubs, toilets, bathtubs, sinks, urinals, toilet bowls, toilet bowl surfaces, other bathroom fixtures, kennel runs, cages, coils and drain pans of air conditioning and refrigeration equipment and heat pumps, conductive flooring and hard nonporous surfaces made of metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, fiberglass, plastic (such as polystyrene, polypropylene), porcelain tiling, enameled surfaces, finished woodwork, Formica®, vinyl and plastic upholstery.

Use **LONZA FORMULATION DC-103** for Poultry Premise Sanitation (Hatcheries) of hard nonporous surfaces in: Egg Receiving Area, Egg Holding Area; Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers and other Poultry House related equipment, and all other hard nonporous surfaces in the Hatchery environment.

Use **LONZA FORMULATION DC-103** for Swine Premise Sanitation of hard nonporous surfaces: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.

Use **LONZA FORMULATION DC-103** for Farm Premise Sanitation of hard nonporous surfaces: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.

**Lonza Formulation DC-103** is a phosphate free, germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. **Lonza Formulation DC-103** has been designed for use between mushroom crops. Areas of intended use include breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds and casing rings. Use of **Lonza Formulation DC-103** should be limited to areas where compost and mushrooms are not present.

**LONZA FORMULATION DC-103** is effective against:

- Avian Infectious Bronchitis Virus
- Avian Influenza Virus
- Canine Distemper Virus
- Newcastle's Disease Virus
- Pseudorabies Virus

**LONZA FORMULATION DC-103** is a one-step (Hospital Use) disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal\* (including HIV-1, the AIDS virus and Hepatitis B Virus), fungicidal, and inhibits the growth of mold and mildew and their odors when used as directed.

**LONZA FORMULATION DC-103** meets AOAC Use-Dilution Test Standards for hospital disinfectants.

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**LONZA FORMULATION DC-103** is a one-step (Hospital use) disinfectant, Bactericidal according to the current AOAC Use-Dilution Test Method, Fungicidal according to the AOAC Fungicidal Test and Virucidal\* according to the virucidal qualification modified in the presence of 400 ppm hard water plus 5% organic serum against:

*(Bacteria:)*

*Pseudomonas aeruginosa* (*Pseudomonas*)  
*Staphylococcus aureus* (*Staph*)  
*Salmonella choleraesuis* (*Salmonella*)

*Acinetobacter baumannii* (*Acinetobacter*)  
*Brevibacterium ammoniagenes* (*Brevibacterium*)  
*Campylobacter jejuni* (*Campylobacter*)  
*Enterobacter aerogenes*  
*Enterococcus faecalis* (*Enterococcus*)  
*Enterococcus faecalis* - Vancomycin resistant (VRE)  
*Escherichia coli* (*E. coli*)  
*Klebsiella pneumoniae* (*Klebsiella*)  
*Pseudomonas cepacia* (*Pseudomonas*)  
*Salmonella schottmuelleri* (*Salmonella*)  
*Salmonella typhi* (*Salmonella*)  
*Serratia marcescens*  
*Shigella dysenteriae* (*Shigella*)  
*Staphylococcus aureus* Methicillin-Resistant (MRSA)  
*Staphylococcus aureus* Multi-Drug Resistant  
*Staphylococcus aureus* - Vancomycin Intermediate Resistant - (VISA)  
*Streptococcus pyogenes* (*Strep*)  
*Vibrio cholerae*

*(Viruses:)*

\*Hepatitis B Virus (HBV)  
 \*Herpes Simplex Virus Types 1 & 2 (Herpes)  
 \*HIV-1 (the AIDS Virus)  
 \*Influenza Type A / Brazil (Influenza)  
 \*Respiratory Syncytial Virus (RSV)  
 \*Vaccinia (Pox Virus)

*(Animal Viruses:)*

Avian Influenza virus  
 Avian Infectious Bronchitis Virus  
 Canine Distemper Virus  
 Newcastle's Disease Virus  
 Pseudorabies Virus

*(Fungi:)*

*Trichophyton mentagrophytes* (the Athlete's Foot Fungus).

*Aspergillus niger*  
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**Lonza Formulation DC-103** is an effective fungicide against *Trichophyton mentagrophytes* (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities.

**LONZA FORMULATION DC-103** is a mildewstat and will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard nonporous surfaces.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

**DISINFECTION / VIRUCIDAL\* DIRECTIONS:**

Apply LONZA FORMULATION DC-103 undiluted to hard, nonporous surfaces with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with brush, sponge or cloth. Avoid breathing spray.

Treated surfaces must remain wet for 10 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry.

After use to disinfect food contact surfaces, rinse with potable water.

For heavily soiled areas, a preliminary cleaning is recommended.

*(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:)*

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

or

This product is not for use on medical device surfaces.

**FUNGICIDAL DIRECTIONS:** For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities, follow disinfection directions. LONZA FORMULATION DC-103 is an effective one-step fungicide against *Trichophyton mentagrophytes*.

**MOLD AND MILDEW CONTROL.** LONZA FORMULATION DC-103 will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces. Follow disinfection directions. Allow to air dry on surface. Repeat when mildew growth returns.

**NON-ACID TOILET BOWL AND URINAL DISINFECTANT / CLEANER DIRECTIONS:**

Remove gross filth prior to disinfection.

Empty toilet or urinal and apply LONZA FORMULATION DC-103 to exposed surfaces and under the rim with a cloth, mop, sponge, or sprayer. Brush or swab thoroughly, allow to stand for 10 minutes, and flush.

**TO CLEAN AND DEODORIZE:** Apply undiluted to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

**FOR USE ON FINISHED FLOORS:** Apply with a damp mop or autoscrubber.

**SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION (BACTERICIDE) / VIRUCIDE / FUNGICIDE DIRECTIONS:**

Use Lonza Formulation DC-103 undiluted to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Use fresh product daily or more often if product becomes diluted or soiled.

**Note:** Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

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**ULTRASONIC BATH DISINFECTANT DIRECTIONS:**

Use LONZA FORMULATION DC-103 to disinfect hard nonporous non-critical objects compatible with Ultrasonic cleaning units. Pour Lonza Formulation DC-103 directly into bath chamber. Pre-clean heavily soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water (sterile water for injection) or allow to air dry. Use fresh product for each use.

**DISINFECTION OF WHIRLPOOL UNITS:** After using the whirlpool unit, drain, and fill with **Lonza Formulation DC-103** to just cover the intake valve. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair lift and any related equipment with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes.

After the unit has been thoroughly cleaned, drain the solution from the unit and rinse cleaned surfaces with fresh water.

Repeat for heavily soiled units.

**KILLS HIV-1 AND HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.**

**PERSONAL PROTECTION:** Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.

**CLEANING PROCEDURE:** Blood and other body fluids containing HIV or HBV must be thoroughly cleaned from surfaces and objects before application of LONZA FORMULATION DC-103.

**CONTACT TIME:** Leave surface wet for 1 minute (60 seconds) for HIV-1 and 10 minutes for HBV. Use a 10 minute contact time for disinfection against all other viruses, bacteria and fungi claimed.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

#### POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:

Remove all animals and feeds from premises, vehicles, and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with **LONZA FORMULATION DC-103** for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, trucks, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

**HATCHERIES:** Use **LONZA FORMULATION DC-103** undiluted to treat the following hard nonporous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 10 minutes or more. Then allow to air dry.

**VEHICLES:** Clean all vehicles including mats, crates, cabs and wheels with high pressure water and **LONZA FORMULATION DC-103**. Use **LONZA FORMULATION DC-103** undiluted to treat all vehicles. Leave all treated surfaces wet for 10 minutes or more.

**SHOE BATH DISINFECTANT DIRECTIONS:** To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of product should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in bath for 10 minutes prior to entering area. Change the bath daily or more often if solution appears diluted or soiled.

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**DRESSING PLANT DISINFECTANT DIRECTIONS:** Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with **Lonza Formulation DC-103**. Scrub to loosen all soils. Surfaces must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

#### VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with **LONZA FORMULATION DC-103** for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

#### FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with **LONZA FORMULATION DC-103** for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

(Note to reviewer: If container is one gallon or less, the following Storage and Disposal statements will be used:)

**STORAGE AND DISPOSAL**

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If container is greater than one gallon, the following Storage and Disposal statements will be used:)

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**PESTICIDE STORAGE**

Do not store on side. Avoid creasing or impacting of side walls.

**PESTICIDE DISPOSAL**

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL**

(Plastic containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Metal containers:) Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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